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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/253,788	02/22/99	ATKINSON	N 114703.100

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EXAMINER	
HORLICK,K	
ART UNIT	**PAPER NUMBER**
1653	5

DATE MAILED: 12/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic...(s)
09/253,788	Haarer
Examiner	**Group Art Unit**
Kenneth R. Horlick	1653

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-18* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2 (3 pages)

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 2 and 6-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 2 is confusing because it cannot be determined what is encompassed by a plasmid host that "allows amplification in *E. coli*". Clarification is required.

B) Claims 6-12 are confusing because it cannot be determined what is meant by "where the known length of the DNA fragment complies with a protocol". Further, it is unclear what is encompassed by "mitochondrial sequencing", which is not a specific known procedure in the art.

C) Claims 11-12 are further confusing because it cannot be determined what is meant by "the shelf life of biological specimens".

D) Claims 11-18 are confusing because of improper Markush language ("list" as opposed to "group").

E) Claims 13-18 are confusing because "sequencing of mitochondrial DNA" would not be considered by one of ordinary skill in the art as an "assay technique".

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ricciardone et al.

This claim is drawn to a method comprising: collecting known biological samples, and adding at least one known DNA fragment into the samples. Applicant is reminded that "intended use" of these steps, such as is provided in the preamble, does not carry patentable weight

Ricciardone et al. disclose standard PCR reactions, in which known biological samples are prepared and primers (DNA of known length and sequence) are added to said samples. As pointed out in In re Mott, 190 U.S.P.Q. 536 (CCPA 1975), "Claims must be given broadest reasonable construction their language will permit in ex parte prosecution, and applicant who uses broad language runs the risk that others may be able to support the same claim with a different disclosure."

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dollinger (US 5,451,505).

These claims are drawn to methods of marking biological samples comprising introducing into said samples at least one known DNA fragment.

Dollinger discloses marking or tagging materials using nucleic acids (taggants), which taggants may subsequently be identified by means such as polymerase chain reaction (PCR) amplification (see abstract; see columns 1-4). The marked material may be any substance, including solids, liquids, and gases.

Dollinger does not explicitly teach application of his taggant methodology to biological samples, such as forensic samples.

One of ordinary skill in the art would have been motivated to apply the taggant methodology of Dollinger to biological samples because this would have clearly been a straightforward, logical application. It was well known and common knowledge in the art that care must be taken with biological samples so as not to contaminate or mix up said samples, particularly with respect to critical situations such as forensic samples wherein analysis may have important consequences. Dollinger clearly discloses that taggants can be used with "any substance", and that the particular applications which are discussed in the patent "are not meant to be limiting, but will serve to offer those of skill an understanding of the versatility of this invention".

4. No claims are free of the prior art.

5. Slater et al. (US 5,665,538) is made of record as a reference of interest.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kenneth Horlick whose telephone number is (703) 308-3905. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers for Group 1600 are (703) 308-4556 and 308-4242.

KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP ~~1800~~ 1600 12/15/99

Kenneth R. Horlick, Ph.D.